K031151

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510(k) SUMMARY

The TS3 Tubing Set serves as a fluid delivery pathway for anticoagulated whole blood from extracorporeal circuits to be delivered to and from a hemoconcentrator. The TS3 Tubing set may be used as a conduit with conventional hemoconcentration during Cardiopulmonary Bypass Surgery or as a conduit for use with the HEMOBAG™ Blood Salvage Device when the bag is used as a hemoconcentrating reservoir.

The TS3 Tubing Set is designed with ¼" ID PVC tubing with standard dialysis luer fittings for connection to a commercially available hemoconcentrator. The TS3 Tubing Set is also designed with quick connect/disconnect fittings for easy attachment to the HEMOBAG™ Blood Salvage Device Reservoir. The tubing sets are manufactured with appropriately sized snap clamps for closing/occluding the tubing when appropriate.

SAFETY TESTING

The sterile TS3 Tubing Set was subjected to Biological Evaluation (biocompatibility testing) using the guidelines provided in ANSI/AAMI/ISO 10993, Vol. 4 for limited exposure medical devices that have contact with circulating blood used in Cardiopulmonary Bypass and extracorporeal circuits. The device successfully passed all of these tests.

The TS3 Tubing set was evaluated together with the HEMOBAG™ to determine whether or not the devices introduced more trauma to the blood than the predicate devices (the predicate device for the HEMOBAG™ is the Medtronic Venous Reservoir Bag). The evaluation was performed by determining the cellular depletion and hemolysis of anticoagulated bovine whole blood that had been circulated through the HEMOBAG™ and TS3 Tubing Set at a rate of approximately 1.2 liters per minute for a 1-hour period. An identical evaluation was performed on the anticoagulated bovine whole blood that had been circulated through the predicate devices (Medtronic Venous Reservoir Bag and Baxter ¼": tubing) in the same manner. The results of these tests proved that the difference between the amount of cellular damage noted in the blood that had been circulated through the HEMOBAG™/TS3 Tubing Set circuit and that which had been circulated through the predicate device circuit was statistically insignificant. Cellular damage was measured by change in hematocrit, platelet depletion, white blood cell count, plasma free hemoglobin evaluation and calculated percent (%) hemolysis. Blood in the test circuits was evaluated and found to have demonstrated acceptable hematologic parameters during the test period. Since the test parameters used are far worse than the parameters that will be used in clinical use, this device is considered safe with respect to cellular damage and hemolysis when used under abnormal stressful conditions.

EFFECTIVENESS

The function and purpose of this device is to allow fluid to flow to and from the hemoconcentrator during conventional hemoconcentration as an adjunct to the Cardiopulmonary Bypass Circuit or as a fluid pathway between the hemoconcentrator and the HEMOBAG™ Blood Salvage Device Reservoir during closed circuit hemoconcentration. The TS3 Tubing set was designed using materials, components and processes that will allow the tubing set to be attached to any commercially available hemoconcentrator and the HEMOBAG™ Blood Salvage Device Reservoir. The TS3 Tubing Set is intended to be used as a fluid pathway for fluid that is circulating at a rate of 300 – 500 ml per minute for approximately 10 – 15 minutes. The device was successfully tested for leaks by applying internal air pressure of 12psi, submerging under water for a 30-second test period and observing the set for air leakage. Since the test parameters represent a scenario far worse than those seen in clinical use, the device is considered effective with respect to its ability to serve as a fluid pathway during hemoconcentration.

APPENDIX D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2003

Global Blood Resources, LLC
Mr. Keith Samolyk, CCP
President & CEO
998 Windsor Avenue
Windsor, CT 06096

Re: K031151
Trade/Device Name: TS3 Tubing Set
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: April 7, 2003
Received: April 10, 2003

Dear Mr. Samolyk:

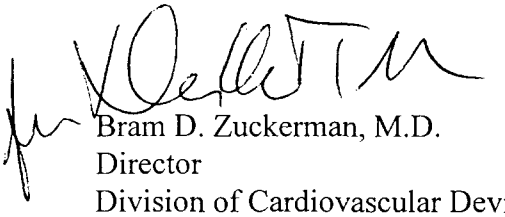
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) - Unknown

Device Name: TS3 Tubing Set

Indications For Use:

The TS3 Tubing Set serves as a fluid delivery pathway for anticoagulated whole blood from extracorporeal circuits to be delivered to and from a hemoconcentrator.

The TS3 Tubing Set may be used in either of the following situations:

a) As a conduit for conventional hemoconcentration during Cardiopulmonary Bypass surgery, or
b) As a conduit for use with the HEMOBAG™ Blood Salvage Device as a hemoconcentration reservoir.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K03115

Prescription Use Only